

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application)	
)	
Inventor(s): Rubinfeld)	
)	Art Unit: Not Yet Assigned
Application No.: Not Yet Assigned)	
)	Examiner: Not Yet Assigned
Filed: Herewith)	
)	
Title: COMBINATION THERAPY)	
INCLUDING 9-NITRO-20(S)-)	
<u>CAMPTOTHECIN AND 5-FLUOROURACIL</u>)	

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicant submits this Preliminary Amendment prior to examination on the merits. Consideration of the above-referenced application is respectfully requested in view of the following amendments and remarks. Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Please amend the above-referenced application as follows:

In the Title:

Please replace the Title with the following new Title:

COMBINATION THERAPY INCLUDING 9-NITRO-20(S)-CAMPTOTHECIN
AND 5-FLUOROURACIL

In the Abstract:

Please replace the abstract on page 20 with the following new rewritten paragraph.

A method for treating a patient having a disease associated with undesirable or uncontrolled cell proliferation such as cancer and restenosis is provided. The method comprises: delivering to the patient a therapeutically effective amount of 9-nitro-20(S)-camptothecin in combination with an effective amount of an antimetabolite such as 5-fluorouracil.

In the Specification

At page 1, prior to the heading "Field of the Invention", please insert the following:

--Related Applications

This application is a continuation of U.S. Patent Application Serial No. 09/709,967, filed November 10, 2000, which is a continuation of U.S. Patent Application Serial No. 09/418,862, filed October 15, 1999, both of which are incorporated herein by reference in their entirety.--

In the Claims

Please cancel claims 1-18.

Please add the following new claims.

- 1 19. A method for treating a patient having a disease associated with undesirable or
- 2 uncontrolled cell proliferation, the method comprising:
- 3 delivering to the patient a therapeutically effective amount of a 9-nitro-20(S)-
- 4 camptothecin; and
- 5 delivering to the patient a therapeutically effective amount of a 5-fluoruracil.

1 20. The method according to claim 19, wherein the 9-nitro-20(S)-camptothecin and 5-
2 fluoruracil are delivered in combination.

1 21. The method according to claim 19, wherein the disease associated with undesirable or
2 uncontrolled cell proliferation is cancer.

1 22. The method according to claim 19, wherein the cancer is selected from the group
2 consisting of acute myelogenous leukemia, cholangiocarcinoma, chronic myelogenous
3 leukemia, lymphoma, melanoma, multiple myeloma, osteosarcoma, gastric sarcoma, glioma,
4 bladder, breast, cervical, colorectal, lung, ovarian, pancreatic, prostate, and stomach cancer.

1 23. The method according to claim 19, wherein the disease associated with undesirable or
2 uncontrolled cell proliferation is restenosis. —

REMARKS

Consideration is respectfully requested in view of the above amendments. Applicants earnestly believe that they are entitled to a letters patent, and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

Date: Feb 11, 2002

By: David J. Weitz
David J. Weitz
Registration No. 38,362

WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Title:

[COMBINATION THERAPY INCLUDING CAMPTOTHECIN]
COMBINATION THERAPY INCLUDING 9-NITRO-20(S)-CAMPTOTHECIN
AND 5-FLUOROURACIL

In the Abstract:

[A method for treating diseases comprises delivering to a patient in need of treatment a therapeutically effective amount of 20(S)-camptothecin, an analog of 20(S)-camptothecin, or a derivative of 20(S)-camptothecin in combination with an effective amount of at least one of an alkylating agent, epidophyllotoxin, antimetabolite, antibiotic or vinca alkaloid.]

A method for treating a patient having a disease associated with undesirable or uncontrolled cell proliferation such as cancer and restenosis is provided. The method comprises: delivering to the patient a therapeutically effective amount of 9-nitro-20(S)-camptothecin in combination with an effective amount of an antimetabolite such as 5-fluorouracil.